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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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DLA PIPER RUDNICK GRAY CARY US, LLP			WESSENDORF, TERESA D	
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DATE MAILED: 09/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/749,532

Applicant(s)

YAMAKAWA ET AL.

Examiner

T. D. Wessendorf

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 20--31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

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DETAILED ACTION

Election/Restrictions

Applicant's election of Group I, claims 1-19 in the reply filed on 9/6/2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 20-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions there being no allowable generic or linking claim. Election was made **without** traverse.

Upon reconsideration of the species restriction, the species restriction is withdrawn.

Status of Claims

Claims 1-31 are pending

Claims 20-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

Claims 1-19 are under examination.

Specification

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors (typographical, grammatical and idiomatic). Applicants'

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cooperation is requested in correcting any errors of which applicants may become aware in the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

To satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107

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F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. See, e.g., Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406; Amgen, Inc. v. Chugai Pharmaceutical, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) (one must define a compound by "whatever characteristics sufficiently distinguish it").

The specification fails to provide an adequate written description for a method for identifying a peptide that binds to a surface having a target geometrical shape. The disclosure does disclose any peptide that has been identified from a phage display library that binds to a target geometrical shape. The description in the disclosure for each of the huge components of the methods is provided only in terms of definition. It does not describe the kind and/or shape assumed by the surface to contain any kind of target. A listing or definition of every possible

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surface or target does not constitute a written description of every species in a genus. It would not "reasonably lead" those skilled in the art to any particular species. In re Ruschig, 379 F.2d 990, 995, 154 USPQ 118, 123 (CCPA 1967). The disclosure is replete with generalities, the exemplification even for a single species is nil. To satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the genus of the invention. Applicants are further referred to the CAFC decision in the University of California vs. Eli Lilly and Co. CAFC 43 USPQ2d 1398 7/22/1997 with respect to adequate disclosure of the scope of the presently claimed method. Adequate disclosure, like enablement, requires representative examples, which provide reasonable assurance to one skilled in the art that the compounds falling within the scope both possess the alleged utility and additionally demonstrate that applicant had possession of the full scope of the claimed invention. See In re Riat (CCPA 1964) 327 F.2d 685, 140 USPQ 471; In re Barr. (CCPA 1971) 444 F.2d 349, 151 USPQ 724 (for enablement) and University of California v. Eli Lilly and Co. (for disclosure).

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Claims 1-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure satisfies the enablement requirement and whether any necessary experimentation is "undue" include:

- (1) the breadth of the claims,
 - (2) the nature of the invention,
 - (3) the state of the prior art,
 - (4) the level of one of ordinary skill;
 - (5) the level of predictability in the art,
 - (6) the amount of direction provided by the inventor,
 - (7) the existence of working examples, and
 - (8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.
- In re Wands*, (U.S.P.Q. 2d 1400 (CAFC 1988)).

1). The specification fails to give adequate direction and guidance in how to readily go about determining the surface having a target geometrical shape e.g., the kind of geometrical shape, the conditions of peptide-target reactions and other undefined factors or variables. It does not describe the kind, type, location and length of peptide in a phage display library.

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2). The specification failed to provide a single working example for a single component included in the innumerable components of the broad claimed scope.

3). The breadth of the claims encompasses a large diversity of surface having a target geometrical shape, phage display library and the other undefined broad components. It is well known in the art that it may be for example, that only a small subset of possible peptide sequences are presented efficiently by a particular phage and/or expression system. And, it is not always easy to follow the expression of peptides in particular cells; for example, to know whether or not a specific cell is expressing a member of the insert, especially for biological methods.

4). The state of the prior art is such that techniques are specifically applied for a predetermined target and/or phage display library.

5). The art is inherently unpredictable because it is not possible to predict which surface containing a target of the required geometrical shape a peptide binds thereto. It is generally known that the conformational freedom that promotes binding, might be restricted which may likely perturb the function and stability of the protein in ways difficult to predict and measure.

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6). Because the art is unpredictable, applicants' specification reasonably would not have assured persons skilled in the art that the numerous undefined components such as peptide, target and surface of any geometrical shape would result in the identification of a peptide from a library without undue experimentation. This is especially true since not a single peptide has obtained from the method. Applicants do not adequately enable persons skilled in the art to readily determine such. Applicants need not guarantee the success of the full scope of the claimed invention. However, skilled artisans are provided with little assurance of success.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35

U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5, 6, 8, 15 and 19 are rejected under 35

U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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A. Claim 5 is indefinite, as the base claim does not recite for the rounds of biopanning.

B. Claim 6, which is dependent on claim 5, is rejected for the same reason above.

C. Claim 8 is confusing as to the language "the phage are contacted with a surface that is substantially identical in composition to the surface..."

D. Claim 19 is indefinite in determining the nucleotide sequence of a phage polynucleotide that encodes the identified peptide, as the base claim does not recite a nucleotide but only peptide.

E. Claim 15 "the flat surface or smooth, curved surface" lacks antecedent basis of support from the base claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the

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effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-10, 16, 18 and 19 are rejected under 35

U.S.C. 102(b) as being anticipated by Naik et al (Nature).

Naik discloses at page 169, cols. 1 and 2 a method of identifying a silver binding peptides from a combinatorial phage display peptide library comprising contacting a phage display peptide library with a inorganic surface, as silver. Naik discloses at page 170 up to page 171 that the silver particles were analyzed by transmission electron microscope. The examination of the silver nanoparticles obtained using AG4 peptide revealed the presence of hexagonal, spherical and triangular silver particles. The silver crystal exhibited a flat plate-like morphology. See further the Methods at page 172 which provide a detail description of the method. The broad claimed method utilizing broad components is fully met by the process of Naik using specific components therein.

Claims 1, 3-7, 10-12, 15, 18 and 19 are rejected under 35

U.S.C. 102(e) as being anticipated by Belcher (US 20030113714).

Belcher discloses in the abstract a method for selective binding of amino acid oligomers to semiconductor and elemental

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carbon-containing materials. Belcher discloses at [0047] that "elemental carbon-containing molecule" generally refers to allotropic forms of carbon. Examples include, but are not limited to, diamond, graphite and highly ordered pyrolytic graphite (HOPG). At paragraph [0048] the "substrate" may be a microfabricated solid surface to which molecules attach through either covalent or non-covalent bonds and includes, e.g., silicon, mica, gold, silver, metal, metal alloy and combinations thereof capable of having functional groups such as amino, carboxyl, thiol or hydroxyl incorporated on its surface. The substrate may be porous, planar or nonplanar. The substrate includes a contacting surface that may be the substrate itself or a second layer (e.g., substrate or biologic material with a contacting surface) made of organic or inorganic molecules and to which organic or inorganic molecules may contact. Belcher discloses that previously it was shown that peptides may bind to semiconductor material. Semiconductor materials useful in binding peptides include, but are not limited to gallium arsenide, indium phosphate, gallium nitrate, zinc sulfide, aluminum arsenide, aluminum gallium arsenide, cadmium sulfide, cadmium selenide, zinc selenide, lead sulfide, boron nitride and silicon. At paragraph [0054] it was disclosed that the method provides a random organic polymer pool using a Phage-display library. A

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Phage-display library is a combinatorial library of random peptides containing between 7 and 12 amino acids fused to the pIII coat protein of M13 coliphage, providing different peptides that are reactive with crystalline semiconductor structures or other materials. At paragraph [0055] peptide sequences have been developed with affinities for various materials such as semiconductors, and elemental carbon-containing molecules such as graphite. At paragraph [0056] Belcher discloses that using a Phage-display library, protein sequences that successfully bound to the specific crystal were eluted from the surface, amplified by, e.g., a million-fold, and reacted against the substrate under more stringent conditions. This procedure was repeated between three and seven times to select the phage in the library with the most specific binding peptides. After, e.g., the third, fourth and fifth rounds of phage selection, crystal-specific phage were isolated and their DNA sequenced, identifying the peptide binding that is selective for the crystal composition (for example, binding to GaAs but not to Si) and crystalline face (for example, binding to (100) GaAs, but not to (111)B GaAs).

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Claims 1, 4-7, 18 and 19 are rejected under 35

U.S.C. 102(b) as being anticipated by Lee et al (Science).

Lee discloses at page 893, Fig. 1 a method of identifying peptide by contacting a phage library with a surface comprising a target with a geometrical shape. See the entire article.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-16 and 18-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over any one of Naik or Belcher or Lee in view of Puentes (Science).

Each of Naik, Belcher and Lee is discussed above. Each of these references does not disclose a surface comprising a surfactant. However Puentes teaches at page 2115 up to page 2117 the use of surfactant. Puentes teaches that the use of surfactant results in the preparation of wide range of shapes including rod, teardrops, and tetrapods and branched tetrapods. The shapes can be made simply by varying surfactant compositions

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as learned from the prototypical CdSe system. Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use a surfactant in the surface of e.g., Naik as taught by Puentes. The advantages taught by Puentes in the use of surfactant composition would provide the motivation to one having ordinary skill in the art at the time the invention was made.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over any one of Naik or Belcher or Lee as applied to claims 1-16 and 18-19 above, and further in view of Freeman et al (Science).

Naik or Belcher or Lee does not disclose a surface with a Teflon as recited in claim 17. However, Freeman at page 1629 teaches a substrate comprising Teflon. Freeman discloses that the Teflon is conventionally used as a substrate. The solution-based process taught by Freeman is extremely general encompassing numerous permutations of insulating and conducting substrates including Teflon. Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use as a surface substrate, Teflon in the method of e.g., Naik as taught by Freeman. The different permutations that can be done to the conventional substrate as Teflon as taught by Freeman would provide the motivation to one

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having ordinary skill in the art, at the time the invention was made.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (571) 272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


T. D. Wessendorf
Primary Examiner
Art Unit 1639

tdw
September 23, 2005